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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/667,193 | 09/19/2003 | Andrew H. Segal | 11111/2003G | 6811 |
| 29933 | 7590 | 09/20/2007 | EXAMINER | |
| PALMER & DODGE, LLP KATHLEEN M. WILLIAMS 111 HUNTINGTON AVENUE BOSTON, MA 02199 | | | LE, EMILY M | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1648 | | |
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| | | 09/20/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/667,193 | SEGAL ET AL. | |
| | Examiner | Art Unit | |
| | Emily Le | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 February 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-16 is/are pending in the application.
 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-8 and 10-16 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1-16 are pending. Claim 9 is withdrawn for being directed to a non-elected invention. Claims 1-8 and 10-16 are under examination.

To allow the entry of the rejection(s) set forth below, this office action is a non-final office action.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-8 and 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoo.¹

The claims are directed to the administration of a composition to an animal to modulate an immune response. The composition comprises an antigen and a fusion polypeptide comprising i) a first amino acid sequence that comprises a cell-surface binding moiety and ii) a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein the antigen and the fusion polypeptide are bounded and unbounded together. Claim 2, which depends on claim 1, limits the animal to a mammal, which is later limited to a human by claim 3. Claim 4, which depends on claim 1, clarifies that the first and second amino acid sequences are

¹ Hoo, W., U.S. Patent No. 5891432, published April 06, 1999.

joined to render a fusion polypeptide. Claims 5-6, which depend on claim 4, require the first amino acid to be N- and C-terminal to the second amino acid sequence, respectively. Claim 7, which depends on claim 1, limits the second amino acid sequence to a ligand for a cytokine receptor, which is limited to GM-CSF, the elected invention, by claim 8. Claim 10, which depends on claim 1, requires the antigen to be a tumor cell, a bacterial cell, a fungal cell, a cell of a parasite, a mammalian cell or an insect cell. Claim 11, which depends on claim 1, requires the antigen to be a pathogenic cell or virus. Claim 12, which depends on claim 1, requires the antigen to be an attenuated cell or virus. Claim 13, which depends on claim 1, requires the antigen to be a cell that is unable to divide. Claim 14, which depends on claim 1, requires the leukocyte to be an antigen presenting cell, which is specified as a professional antigen presenting cell by claim 15 and dendritic cell by claim 16.

Hoo teaches the administration of a composition to an animal to modulate an immune response. [Claims 13-24, in particular.] The composition of Hoo comprises an antigen and a fusion polypeptide. [Claims 1-12, in particular.] In the composition of Hoo, the antigen and the fusion polypeptide are bounded and unbounded together. [Claim 1 and claim 12, in particular.] The antigen that Hoo teaches includes a virus, a bacterial cell, fungal cell, a cell of a parasite, a mammalian cell, pathogenic and attenuated antigens, and a cell that is substantially unable to divide. [Lines 35-45, column 10, and columns 9-18, in particular.]

The first amino acid sequence in the fusion polypeptide of Hoo comprises the sequence to a membrane attachment domain, a cell-surface binding moiety. The

second amino acid sequence in the fusion polypeptide of Hoo comprises the sequence of a ligand for a cell surface polypeptide of a leukocyte. Specifically, the ligand for a cell surface polypeptide of a leukocyte is a ligand for a cytokine receptor. In particular, the ligand for a cytokine receptor that Hoo et al. teaches is GM-CSF. [Example I, column 22, in particular.] The ligand for a cell surface polypeptide used by Hoo is a ligand for a ligand for a cell surface polypeptide of a leukocyte, wherein the leukocyte is dendritic cells, which is a professional antigen presenting cell. [Columns 1-2, in particular.] Hoo teaches that the first amino acid sequence can be N-terminal and C-terminal to the second amino acid sequence.

In the instant case, the composition of Hoo et al. is the same as the claimed invention. Therefore, the claimed invention is anticipated by Hoo.

Conclusion

4. No claims are allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily M. Le/
Patent Examiner
Art Unit 1648

/E.Le/